it satisfies the requirements of the applicable statutes and regulations.

## IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## V. Electronic Access

Persons with access to the internet may obtain the draft guidances at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–10589 Filed 5–19–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0406]**

### Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1); Draft Information Sheet Guidance for Sponsors, Clinical Investigators, and Institutional Review Boards; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft information sheet guidance for sponsors, clinical investigators, and institutional review boards (IRBs) entitled ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1).'' This draft guidance partially revises the final information sheet guidance for sponsors, clinical investigators, and IRBs entitled ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572)'' (May 2010) (the Form FDA 1572 FAQ Guidance) to explain FDA's current thinking regarding waivers of the signature requirement for Form FDA 1572. This draft guidance proposes to revise responses to frequently asked questions 10, 11, and 13 from the Form FDA 1572 FAQ Guidance by including information regarding the waiver of the Form FDA 1572 signature requirement and proposes a new section regarding signature waivers.

**DATES:** Submit either electronic or written comments on the draft guidance by July 19, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2008–D–0406 for ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Paul Gouge, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, Rm. 6328, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3093, *paul.gouge@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft information sheet guidance for sponsors, clinical investigators, and IRBs entitled ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1).'' The draft guidance proposes to revise responses to the following questions from the Form FDA 1572 FAQ Guidance:

- Question 10: Must investigators who conduct studies outside the United States sign a 1572?
- Question 11: If a foreign clinical study is being conducted under an IND [investigational new drug application], what are the investigator's responsibilities with respect to regional, national, or local laws and regulations?
- Question 13: If a sponsor chooses to conduct a foreign clinical study under an IND and the investigators at the non-U.S. sites follow the recommendations in the [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use] ICH E6 Good Clinical Practice Consolidated Guidance, would the non-U.S. investigators also be in compliance with FDA's IND requirements under 21 CFR part 312?

The above questions now include reference to the Form FDA 1572 waiver process. Further, the draft guidance proposes the addition of a new section describing the Agency's current thinking regarding the Form FDA 1572 signature waiver process. The new section is entitled ''Section #9: Form FDA 1572 Signature Waiver.'' This new section outlines the process for submitting requests to FDA for waivers from the Form FDA 1572 signature requirements when investigators cannot or will not sign the Form FDA 1572 for clinical studies conducted in foreign countries, and the sponsor wishes to conduct the study at the foreign sites under an IND. The new section also provides information regarding the documentation that may be included in the 1572 signature waiver request.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). Based on the comments received to the docket, we intend to revise the Form FDA 1572 FAQ Guidance to amend our responses to questions (such as general questions 10, 11, and 13) from that document and to include a new section (see questions 39 through 46 of the draft guidance) about waivers of the Form FDA 1572 signature requirement, the subjects addressed in this draft guidance. This draft guidance is not intended to be finalized as a separate guidance document but will be consolidated with the Form FDA 1572 Guidance and issued as one comprehensive guidance. When finalized, the consolidated guidance will represent the current thinking of FDA on ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–10612 Filed 5–19–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Medical Reserve Corps Request for Information

**AGENCY:** Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

**ACTION:** Request for information.

**SUMMARY:** The American Rescue Plan provides $100 million to the Medical Reserve Corps (MRC) program. To inform a strategic and impactful plan for execution of this funding, HHS is issuing this Request for Information (RFI). The RFI solicits specific input regarding current strengths and needs of MRC units and stakeholders, resource gaps highlighted during the COVID–19 response, and recommendations for short- and long-term priorities for the MRC. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

**DATES:** To be considered, public comments must be received electronically no later than midnight eastern standard time (EST) 30 days after posting.

**ADDRESSES:** Public comments should be submitted online at *http://www.regulations.gov.* All submissions must be submitted to the Docket named HHS–ASPR–2021–0013 to ''Request for Information (RFI) from Non-Federal Stakeholders: Advancing the Medical Reserve Corps with the American Rescue Plan.'' Comments submitted electronically, including attachments, will be posted to the docket unchanged and available to view by the public. Evidence and information supporting your comment can be submitted as attachments. Please provide your contact information or organization name on the web-based form for possible follow up from HHS. There is a 5,000 character limit on comments and maximum number (10) of attached files and maximum size (10 MB) of each attached file.

**FOR FURTHER INFORMATION CONTACT:** Esmeralda Pereira, MSPH, Director, Medical Reserve Corps Program, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, Washington, DC, (202) 205–0065 or *esmeralda.pereira@hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The Volunteer Medical Reserve Corps is authorized by Section 2813 of the Public Health Service Act [42 U.S.C. 300hh–15]. The MRC program supports a national network of over 200,000